Complete Summary

GUIDELINE TITLE

NIH State-of-the-Science Conference Statement on cesarean delivery on maternal request.

BIBLIOGRAPHIC SOURCE(S)

NIH State-of-the-Science Conference Statement on cesarean delivery on maternal request. NIH Consens State Sci Statements 2006 Mar 27-29;23(1):1-29. [63 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Childbirth by cesarean delivery

GUIDELINE CATEGORY

Counseling
Management
Prevention
Risk Assessment

CLINICAL SPECIALTY

Anesthesiology
Internal Medicine
Nursing
Obstetrics and Gynecology
Pediatrics
Preventive Medicine
Urology

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Nurses
Patients
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

To provide health care providers, patients, and the general public with a responsible assessment of currently available data on cesarean delivery on maternal request

TARGET POPULATION

Pregnant women requesting scheduled cesarean delivery

INTERVENTIONS AND PRACTICES CONSIDERED

1. Evaluation of benefits and risks of cesarean delivery on maternal request
2. Patient-individualized decision to perform cesarean delivery (consistent with ethical principles)

MAJOR OUTCOMES CONSIDERED

- Benefits and risks of planned vaginal versus planned cesarean delivery
- Maternal outcomes
    - Hemorrhage
    - Length of hospital stay
    - Infection
    - Anesthetic complications
    - Subsequent placenta previa
    - Breastfeeding
    - Urinary incontinence
    - Surgical and traumatic complications
    - Subsequent uterine rupture
    - Hysterectomy
    - Subsequent fertility
    - Anorectal function

    - Sexual function
    - Pelvic organ prolapse
    - Subsequent stillbirth
    - Maternal mortality
- Neonatal outcomes
    - Respiratory morbidity
    - Iatrogenic prematurity
    - Length of hospital stay
    - Fetal mortality
    - Intracranial hemorrhage, asphyxia, and encephalopathy
    - Brain injury and laceration
    - Neonatal infection

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): A systematic review of the literature was prepared by the RTI International-University of North Carolina Evidence-based Practice Center for the Agency for Healthcare Research and Quality for use by the National Institutes of Health (see the "Availability of Companion Documents" field).

MEDLINE®, Cochrane Collaboration resources, and Embase were searched. Evidence-based Practice Center (EPC) staff also hand-searched the reference lists of relevant articles to make sure that any relevant studies were not being missed. The Technical Expert Panel (TEP) was consulted about any studies or trials that are currently under way or that may not be published yet. Based on the inclusion/exclusion criteria (see Chapter 2 of the Evidence Report ["Availability of Companion Documents" field]), a list of Medical Subject Heading (MeSH) search terms was generated (refer to Appendix A of the Evidence Report [see the "Availability of Companion Documents" field]). The TEP also reviewed these terms to ensure that any critical areas were not being missed, and this list represents collective decisions as to the MeSH terms used for all searches.

Based on key questions and discussion with the TEP, a list of article inclusion and exclusion criteria was generated. Studies were excluded that: (1) did not report on women of reproductive age; (2) were published in languages other than English; (3) did not report information pertinent to the key clinical questions; (4) had fewer than 50 subjects for randomized controlled trials (RCTs) or 100 subjects for observational studies; and (5) were not original studies. Additionally, and in consultation with the TEP, studies were excluded that did not provide data on both planned cesarean delivery and planned vaginal delivery for KQ 1 and KQ 2. The searches were limited to articles published in or after 1990 because of the

significant advances in operative techniques, anesthesia, availability of antibiotics, and neonatal care over the past several decades that have resulted in a decline in maternal and neonatal mortality. EPC staff also restricted their searches to developed countries so that they could have comparable data on the standard of care. Based on recommendations from the TEP, they tracked citations from Brazil, which has long been documented to have high rates of cesarean deliveries; however, no study from Brazil met the inclusion criteria. (The inclusion and exclusion criteria are documented in Table 3 of the Evidence Report and Figure 3 of the Evidence Report, [see the "Availability of Companion Documents" field], presents the yield and results from the search, which was conducted from April through June 2005).

Refer to Chapter 2 in the Evidence Report for further information.

NUMBER OF SOURCE DOCUMENTS

Unique full text articles included in review: n=69

- Key Question (KQ)1=13
- KQ 2=54
- KQ 3=5

(Articles can apply to more than one Key Question)

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

I. **Strong**: The evidence is from studies of strong design; results are both clinically important and consistent with minor exceptions at most; results are free from serious doubts about generalizability, bias, or flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.
II. **Moderate**: The evidence is from studies of strong design, but some uncertainty remains because of inconsistencies or concern about generalizability, bias, research design flaws, or adequate sample size. Alternatively, the evidence is consistent but derives from studies of weaker design.
III. **Weak**: The evidence is from a limited number of studies of weaker design. Studies with strong design either have not been done or are inconclusive.
IV. **No evidence**: No published literature.

This rating scheme follows the criteria applied by West SL, King V, Carey TS et al. Systems to Rate the Strength of Scientific Evidence. Evidence Report, Technology Assessment No. 47. Rockville, Md.: Agency for Healthcare Research and Quality. AHRQ Publication No. 02-E016;2002.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): A systematic review of the literature was prepared by the RTI International-University of North Carolina Evidence-based Practice Center for the Agency for Healthcare Research and Quality for use by the National Institutes of Health (see the "Availability of Companion Documents" field).

Each abstract and article were systematically reviewed against *a priori* criteria to determine inclusion in the review. Two reviewers separately evaluated the abstracts for inclusion or exclusion. If one abstractor concluded that the article should be included in the review, it was retained. Each excluded article was assigned a reason for exclusion. Data from abstraction forms were entered into evidence tables and checked for consistency and accuracy. Staff reconciled all disagreements about information in evidence tables. Articles excluded at the full-article review stage and reasons for their exclusion are listed in Appendix D (of the Evidence Report [see the "Availability of Companion Documents" field]). Refer also to the Evidence Report for additional information.

The evidence was systematically reviewed on three Key Questions: (1) trend and incidence of cesarean delivery over time, (2) effect of approach to delivery (cesarean delivery on maternal request compared with planned vaginal delivery) on maternal and neonatal outcomes, and (3) factors that affect the magnitude of the benefits and harms identified in Key Question 2.

Refer to Chapter 2 in the Evidence Report (see the "Availability of Companion Documents" field) for further information.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Consensus Development Conference)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The National Institute of Child Health and Human Development and the Office of Medical Applications of Research of the National Institutes of Health convened a State-of-the-Science Conference from March 27 to 29, 2006, to assess the available scientific evidence on cesarean delivery on maternal request.

An impartial, independent panel was charged with reviewing the available published literature in advance of the conference, including a systematic literature review commissioned through the Agency for Healthcare Research and Quality.

Answering the Key Questions below, the non-Department of Health and Human Services, nonadvocate 18-member panel representing the fields of obstetrics and gynecology, preventive medicine, biometrics, family planning and reproductive physiology, nurse midwifery, anesthesiology, patient safety, epidemiology,

pediatrics, perinatal medicine, urology, urogynecology, general nursing, inner city public health sciences, law, psychiatry, and health services research drafted a statement based on scientific evidence presented in open forum and on the published scientific literature:

- What are the trends and incidence of cesarean delivery over time in the United States and other countries (when possible, separate by intent)?
- What are the short-term (under 1 year) and long-term benefits and harms to mother and baby associated with cesarean delivery by request versus attempted vaginal delivery?
- What factors influence benefits and harms?
- What future research directions need to be considered to get evidence for making appropriate decisions regarding cesarean delivery on request or attempted vaginal delivery?

The panel drafted its statement based on scientific evidence presented in open forum and on published scientific literature. The draft statement was presented on the final day of the conference and circulated to the audience for comment. The panel released a revised statement later that day at http://consensus.nih.gov.

Refer to the original guideline document and Chapter 2 in the Evidence Report (see the "Availability of Companion Documents" field) for further information.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Guideline developers reviewed published cost analyses.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The RTI International-University of North Carolina Evidence-based Practice Center requested review of this report from a wide array of individual outside experts in the field, including the Technical Expert Panel (TEP), and from relevant professional societies and public organizations. The Agency for Healthcare Research and Quality (AHRQ) also requested review from its own staff and appropriate federal agencies. Initially 33 individuals or organizations were asked about their interest and availability for peer review. Ultimately, 18 invitations for peer review were sent: to 5 TEP members, 6 relevant organizations, and 7 individual experts. Reviewers included clinicians (e.g., obstetrics, urogynecology, family practice, pediatrics), representatives of professional societies and advocacy groups, and potential users of the report.

Peer reviewers were charged with commenting on the content, structure, and format of the evidence report, providing additional relevant citations, and pointing out issues related to how Evidence-based Practice Center (EPC) staff had conceptualized and defined the topic and key questions. Peer reviewers were also asked to complete a peer review checklist. Fifteen responses were received in addition to comments from AHRQ staff. The individuals listed in Appendix E of the Evidence Report (see the "Availability of Companion Documents" field) gave permission to acknowledge their review of the draft. EPC staff compiled all comments and addressed each one individually, revising the text as appropriate.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

- The incidence of cesarean delivery without medical or obstetric indications is increasing in the United States, and a component of this increase is cesarean delivery on maternal request. Given the tools available, the magnitude of this component is difficult to quantify.
- There is insufficient evidence to evaluate fully the benefits and risks of cesarean delivery on maternal request as compared to planned vaginal delivery, and more research is needed.
- Until quality evidence becomes available, any decision to perform a cesarean delivery on maternal request should be carefully individualized and consistent with ethical principles.
- Given that the risks of placenta previa and accrete rise with each cesarean delivery, cesarean delivery on maternal request is not recommended for women desiring several children.
- Cesarean delivery on maternal request should not be performed prior to 39 weeks of gestation or without verification of lung maturity, because of the significant danger of neonatal respiratory complications.
- Maternal request for cesarean delivery should not be motivated by unavailability of effective pain management. Efforts must be made to assure availability of pain management services for all women.
- National Institutes of Health (NIH) or another appropriate federal agency should establish and maintain a Web site to provide up-to-date information on the benefits and risks of all modes of delivery.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate decision-making regarding cesarean delivery on maternal request
- Improved maternal, fetal, and neonatal outcomes after cesarean delivery on maternal request

POTENTIAL HARMS

Maternal Complications

- The risks of placenta previa and placenta accreta rise with each cesarean delivery. Therefore, in women with multiple cesarean deliveries, the likelihood of hysterectomy is elevated.
- Planned cesarean deliveries have higher infection rates than vaginal deliveries.

Neonatal Complications

- *Respiratory morbidity*. Evidence indicates that respiratory morbidity, which is sensitive to gestational age, is higher for cesarean deliveries than for vaginal deliveries. Studies consistently report increasing respiratory morbidity with elective cesarean delivery compared to planned vaginal delivery with gestational ages earlier than 39–40 weeks of gestation. Infrequently, infants can develop severe respiratory failure and pulmonary hypertension.
- *Iatrogenic prematurity*. There is an approximate doubling of the rates of respiratory symptoms and other problems of neonatal adaptation (e.g., hypothermia, hypoglycemia) and neonatal intensive care unit (NICU) admissions for infants delivered by cesarean delivery for each week below 39–40 weeks of gestation. Therefore, cesarean delivery on maternal request may be associated with a number of neonatal morbidities.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- The statement reflects the panel's assessment of medical knowledge available at the time the statement was written. Thus, it provides a "snapshot in time" of the state of knowledge on the conference topic. When reading the statement, keep in mind that new knowledge is inevitably accumulating through medical research.
- This statement is an independent report of the panel and is not a policy statement of the National Institutes of Health (NIH) or the Federal Government. A final copy of this statement is available, along with other recent conference statements, at the same web address of http://consensus.nih.gov.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

NIH State-of-the-Science Conference Statement on cesarean delivery on maternal request. NIH Consens State Sci Statements 2006 Mar 27-29;23(1):1-29. [63 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006 Mar 27-29

GUIDELINE DEVELOPER(S)

National Institutes of Health (NIH) State-of-the-Science Panel - Independent Expert Panel

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

National Institutes of Health State-of-the-Science Panel

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Panel Members: Mary E. D'Alton, M.D., (*Panel and Conference, Chairperson*); Willard C. Rappleye Professor of Obstetrics and Gynecology, Chair, Department of Obstetrics and Gynecology, Director, Obstetrics and Gynecology, Services, Columbia, University Medical Center, College of Physicians and Surgeons, Columbia University, New York, New York; Michael P. Aronson, M.D., Professor of Obstetrics and Gynecology, University of Massachusetts, Medical School, Director of Women's Health Services, University of Massachusetts, Memorial Medical Center, Worcester, Massachusetts; David J. Birnbach, M.D., Professor and Executive, Vice Chairman, Department of Anesthesiology, Chief, Women's Anesthesia, Jackson Memorial Hospital, Director, University of Miami, Jackson Memorial Hospital, Center for Patient Safety, Miller School of Medicine, University of Miami, Miami, Florida; Michael B. Bracken, Ph.D., M.P.H., FACE; Susan Dwight Bliss, Professor of Epidemiology, Professor of Obstetrics, Gynecology, Reproductive Science, and Neurology, Center for Perinatal, Pediatric and Environmental Epidemiology, Yale University, New Haven, Connecticut; M. Yusoff Dawood, M.D., Professor of Obstetrics and Gynecology, Professor of Physiology, Sanger Chair in Family Planning and Reproductive Physiology, West Virginia University, School of Medicine, Health Sciences Center, Morgantown, West Virginia; William G. Henderson, Ph.D., M.P.H., Professor and Biostatistics, Core Director, University of Colorado Health, Outcomes Program Professor, Department of Preventive Medicine and Biometrics, University of Colorado, Aurora, Colorado; Barbara Hughes, C.N.M., M.S., M.B.A., FACNM, Director of Nurse-Midwifery, Exempla Saint Joseph Hospital, Clinical Faculty University of Colorado Health Sciences Center, Denver, Colorado; Alan H. Jobe, M.D., Ph.D., Professor of Pediatrics, University of Cincinnati, Division of Pulmonary Biology, Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio; Vern L. Katz, M.D., Clinical Professor of Obstetrics and Gynecology, Oregon Health Science University, Adjunct Professor, Department Physiology, University of Oregon, Medical Director of Perinatal Services, Department of Obstetrics and Gynecology, Sacred Heart Medical Center, Eugene, Oregon; Stephen R. Kraus, M.D., FACS, Assistant Professor and Deputy Chairman, Department of Urology, University of Texas Health, Science Center at San Antonio, San Antonio, Texas; Meg Mangin, R.N., Dunn County Home Health Care Menomonie, Wisconsin; JoAnn Elizabeth Matory, M.D., Clinical Associate Professor of Pediatrics, Department of Pediatrics, Indiana School of Medicine; James Whitcomb Riley, Hospital for Children, Indianapolis, Indiana; Thomas R. Moore, M.D., Professor and Chairman, Department of Reproductive Medicine, School of Medicine, University of California, San Diego Medical Center, San Diego, California; Patricia J. O'Campo, Ph.D., Professor, Public Health Sciences, University of Toronto, Alma and Baxter Ricard Chair in Inner City Health, Director, Inner City Health Research Unit, St. Michael's Hospital, Toronto, Canada; Jeffrey F. Peipert, M.D., M.P.H., M.H.A., Vice Chair of Clinical Research, Professor, Department of Obstetrics and Gynecology, Washington University in St. Louis School of Medicine, St. Louis, Missouri; Karen H. Rothenberg, J.D., M.P.A., Dean and Marjorie Cook, Professor of Law, University of Maryland, School of Law, Baltimore, Maryland; Meir Jonathan Stampfer, M.D., Dr.P.H., Professor of Medicine, Professor of Epidemiology and Nutrition, Chair, Department of Epidemiology, Harvard School of Public Health, Boston, Massachusetts; Kimberly A. Yonkers, M.D., Associate Professor, Department of Psychiatry, Department of Epidemiology and Public Health, Yale School of Medicine, New Haven, Connecticut

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All of the panelists who participated in this conference and contributed to the writing of this statement were identified as having no financial or scientific conflict of interest, and all signed forms attesting to this fact. Unlike the expert speakers who present scientific data at the conference, the individuals invited to participate on National Institutes of Health (NIH) Consensus and State-of-the-Science panels are reviewed prior to selection to assure that they are not proponents of an advocacy position with regard to the topic and are not identified with research that could be used to answer the conference questions.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the National Institutes of Health (NIH) Consensus Development Conference Program Web site.

Print copies: Available from the NIH Consensus Development Program Information Center, PO Box 2577, Kensington, MD 20891; Toll free phone (in U.S.), 1-888-NIH-CONSENSUS (1-888-644-2667); autofax (in U.S.), 1-888-NIH-CONSENSUS (1-888-644-2667); e-mail: consensus_statements@mail.nih.gov.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- NIH State-of-the-Science Conference: Cesarean Delivery on Maternal Request. 2006 Mar. 115 p. Available in Portable Document Format (PDF) from the National Institutes of Health (NIH) Consensus Development Conference Program Web site.
- Cesarean delivery on maternal request. 2006 Mar. Available from the AHRQ Web site.

PATIENT RESOURCES

None available

NGC STATUS

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